REMARKS

Status of the claims

Upon entry of these remarks, claims 1, 17, 19 and 26-164 will be pending in this application. New claims 26-164 have been provisionally elected, *with traverse*.

New claims 26-164, which correspond to provisionally elected Group IV (see below) have been added. Support for the newly added claims is found throughout the specification as filed, and no new matter had been introduced.

More particularly, support for new claims directed to using antibodies that specifically bind Neutrokine-alpha polypeptides to treat immune system disorders may be found, for example, on pages 310-366. More particularly, support for new claims directed to using antibodies that specifically bind Neutrokine-alpha polypeptides to treat autoimmune disorders may be found, for example, on pages 20-21 and 333-337. Treatment of rheumatoid arthritis is specifically disclosed for example in the first paragraph of page 336. Support for new claims directed to using antibodies that specifically bind Neutrokine-alpha polypeptides to treat immunodeficiencies may be found, for example, on pages 18-20 and 322-324. Support for new claims directed to using antibodies that specifically bind Neutrokine-alpha polypeptides to treat inflammatory diseases and disorders may be found, for example, on pages 337-338. Support for new claims directed to using antibodies that specifically bind Neutrokine-alpha polypeptides to treat tumors may be found, for example, on pages 18 and 341-342.

Additionally, support for new claims directed to antibodies of the invention can be found, for example, on pages 228-310. Support for new claims directed to monoclonal and polyclonal antibodies and Fab fragments of antibodies can be found, for example, on pages 228-229. Support for new claims directed to labeled antibodies, or antibodies conjugated to a therapeutic or cytotoxic agent can be found, for example, on pages 252-254. Thus, no new matter has been added by way of amendment.

Provisional Election with Traverse

The Examiner has required restriction of the claims into three groups - Group I drawn to a nucleic acid molecule encoding Neutrokine-alpha protein, a vector, a host cell and a method of making the protein represented by claims 1-16, 21, 23, and 24; Group II

drawn to a Neutrokine-alpha polypeptide represented by claim 17, 18, 20, and 22; and Group III represented by claims 19 and 25 drawn to an antibody to Neutrokine-alpha. In response, and pursuant to MPEP § 818.02(a), Applicants provisionally elect, *with traverse*, the subject matter of new claims 26-164, drawn to methods of using antibodies that specifically bind the protein of SEQ ID NO:2 or fragments or variants thereof for treating immune system disorders, for stimulating leukocyte proliferation using Neutrokine-alpha polypeptides, and for enhancing host defenses against infection using Neutrokine-alpha polypeptides, for further prosecution. Applicants submit that the subject matter of new claims 26-164 while fully supported by the specification as filed, does not fall within the scope of the Groups defined by the Examiner in the Office Action, but nonetheless form a single group of claims (hereafter referred to as Group IV) organized according to the scheme set forth by the Examiner in the Restriction Requirement. Under MPEP § 818.02(a) though, an election may be made by the presentation of original claims. Applicants reserve the right to file one or more divisional applications directed to non-elected groups should the restriction requirement be made final.

Applicants respectfully traverse the restriction requirement. Even assuming, for the sake of argument, that patentably distinct inventions appear in an application, restriction remains improper unless it can be shown that the search and examination of each group would entail a "serious burden" (*see* M.P.E.P. § 803). Applicants disagree with The Examiner's assertion that it would impose an undue burden to examine the nucleic acid, polypeptide, antibody (and method) claims together.

Applicants submit the searching the claims together would ease the Examiner's burden because the searches for the different groups are overlapping. Applicants put forth that a search of the polynucleotide claims would clearly provide useful information for the polypeptide claims. For example, in many if not most publications, where a published nucleotide sequence contains an open reading frame, the authors also include, as a matter of routine, the deduced amino acid sequence. Thus, the searches for polynucleotides and polypeptides commonly overlap. Even in the relatively uncommon case where a publication contains a nucleotide sequence which is not accompanied by the corresponding deduced amino acid sequence, it is routine for one to determine the corresponding amino acid sequence. Moreover, a search for Neutrokine-alpha polypeptides would include, also as a matter of routine, a search for antibodies specific for

Neutrokine-alpha and methods of using said antibodies (e.g., subject matter of Group IV, newly added claims 26-164). Thus, the search and examination of a polynucleotide, corresponding deduced polypeptide sequences, antibodies specific for the corresponding deduced polypeptide sequences, and methods of using said antibodies would not entail a serious burden.

Thus, in view of M.P.E.P. § 803, all of the claims should be searched and examined in the subject application. Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application.

CONCLUSION

Applicants respectfully request that the remarks above be entered and made of record in the file history of the instant application.

Respectfully submitted,

Dated: August 20, 2001

Kenley K. Hoover (Reg. No. 40,302)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (301) 610-5771

KKH/MS/cmp

Via Hand Delivery August 20, 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Yu et al.

Application No.: 09/589,288 Art Unit: 1646

Filed: June 8, 2000 Examiner: Prasad, S

For: Neutrokine-alpha and Neutrokine-alpha Splice Variant Atty Docket No.: PF343P3C5

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 2-16, 18, and 20-25 have been cancelled without prejudice.

New claims 26 to 164 have been added.

Respectfully submitted,

Dated: August 20, 2001

Kenley K. Hoover (Reg. No. 40,302)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (301) 610-5771

KKH/MS/cmp

List of Independent Claims

For the Examiner's convenience, Applicants include this list of the set of independent claims filed on August 20, 2001 in 09/589,288.

26. (New) A method of treating an immune system disease or disorder comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of amino acid residues 1 to 285 of SEQ ID NO:2; and

(b) the amino acid sequence of amino acid residues 72 to 285 of SEQ ID NO:2.

39. (New) A method of treating an immune system disease or disorder comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of amino acid residues n to 285 of SEQ ID NO:2, where n is an integer in the range of 2-190;

(b) the amino acid sequence of amino acid residues 1 to m of SEQ ID NO:2, where m is an integer in the range of 274 to 284; and

53. (New) A method of treating an immune system disease or disorder comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence of amino acid residues 134-285 of SEQ ID NO:2.

64. (New) A method of treating an autoimmune disease or disorder comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of amino acid residues 1 to 285 of SEQ ID NO:2; and

(b) the amino acid sequence of amino acid residues 72 to 285 of SEQ ID NO:2.

74. (New) A method of treating an autoimmune disease or disorder comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of amino acid residues n to 285 of SEQ ID NO:2, where n is an integer in the range of 2-190;

(b) the amino acid sequence of amino acid residues 1 to m of SEQ ID NO:2, where m is an integer in the range of 274 to 284; and

(c) the amino acid sequence of amino acid residues n to m of SEQ ID NO:2, where n is an integer in the range of 2-190 and m is an integer in the range of 274-284.

85. (New) A method of treating an autoimmune system disease or disorder comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence of amino acid residues 134-285 of SEQ ID NO:2.

92. (New) A method of treating an immunodeficiency comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of amino acid residues 1 to 285 of SEQ ID NO:2; and

(b) the amino acid sequence of amino acid residues 72 to 285 of SEQ ID NO:2.

101. (New) A method of treating an immunodeficiency comprising administering to an individual, a therapeutically effective amount of an antibody or portion

thereof that specifically binds a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of amino acid residues n to 285 of SEQ ID NO:2, where n is an integer in the range of 2-190;

(b) the amino acid sequence of amino acid residues 1 to m of SEQ ID NO:2, where m is an integer in the range of 274 to 284; and

(c) the amino acid sequence of amino acid residues n to m of SEQ ID NO:2, where n is an integer in the range of 2-190 and m is an integer in the range of 274-284.

111. (New) A method of treating an immunodeficiency comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of the amino acid sequence of amino acid residues 134-285 of SEQ ID NO:2.

118. (New) A method of treating an rheumatoid arthritis comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of the amino acid sequence of amino acid residues 134-285 of SEQ ID NO:2.

131. (New) A method of treating an immune system disease or disorder comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of an amino-terminal deletion protein mutant of the full-length protein encoded by the cDNA clone contained in ATCC Deposit Number 97768, wherein said amino-terminal deletion protein mutant excludes up to 190 amino acid residues from the amino terminus of said full-length protein encoded by the cDNA clone contained in ATCC Deposit Number 97768;

(b) the amino acid sequence of a carboxy-terminal deletion protein mutant of the full-length protein encoded by the cDNA clone contained in ATCC Deposit Number 97768, wherein said carboxy-terminal deletion protein mutant excludes up to 11

amino acid residues from the carboxy terminus of said full-length protein encoded by the cDNA clone contained in ATCC Deposit Number 97768; and

(c) the amino acid sequence of an amino- and carboxy-terminal deletion protein mutant of the full-length protein encoded by the cDNA clone contained in ATCC Deposit Number 97768, wherein said amino- and carboxy-terminal deletion protein mutant excludes up to 190 amino acid residues from the amino terminus and up to 11 amino acid residues from the carboxy terminus of said said full-length protein encoded by the cDNA clone contained in ATCC Deposit Number 97768.

148. (New) A method of inhibiting leukocyte activation or proliferation comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of amino acid residues n to 285 of SEQ ID NO:2, where n is an integer in the range of 2-190;

(b) the amino acid sequence of amino acid residues 1 to m of SEQ ID NO:2, where m is an integer in the range of 274 to 284; and

(c) the amino acid sequence of amino acid residues n to m of SEQ ID NO:2, where n is an integer in the range of 2-190 and m is an integer in the range of 274-284.

158. (New) A method of inhibiting leukocyte activation or proliferation comprising administering to an individual, a therapeutically effective amount of an antibody or portion thereof that specifically binds a protein consisting of an amino acid sequence of amino acid residues 134-285 of SEQ ID NO:2.